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SYSTEMS AND METHODS FOR MIXING AND DISPENSING FLOWABLE MATERIALS

FIELD OF THE INVENTION

The invention relates to systems and methods for mixing materials together, particularly for use in the medical field.

BACKGROUND OF THE INVENTION

Current methods and apparatus for mixing a plurality of materials together in the medical field, e.g., poly(methamylcrylate) bone cement comprising a powdered material with a liquid monomer to be used as a bone filling material, often yield unsatisfactory results.

Typically, in a surgical setting, the instruments employed for this purpose are a small bowl for receiving the components and a common tongue depressor for mixing the components in the bowl. If a powdered material is employed, it is usually poured directly from its container into the bowl. Consequently, the process is often messy due to spillage of the powdered material. Where one of the components is a liquid monomer, the process can involve the release of noxious fumes released by the liquid monomer.

After the components are mixed, as in the case of a bone filling material, further problems are encountered. When the bone filling material is to be dispensed into a cavity in bone, the common practice is to first pour the

filler into a measuring cup. However, due to the consistency of the filler, it often adheres to the sides of the measuring cup, thus obscuring the actual level of filler in the cup. Next, the relatively large tongue depressor is used to transfer filler to a relatively small syringe - all in all an extremely inefficient and messy process.

SUMMARY OF THE INVENTION

Although various manufacturers of medical products have attempted to develop, manufacture and supply various systems for mixing and/or dispensing poly(methamylacrylate) bone cement (e.g., DePuy - see PCT Publication No. WO97/21485, Immedica - see PCT Publication No. WO99/37256, and Stryker - see U.S. Patent No. 6,042,262) such systems are often expensive, too complex, require extensive accessories, or cannot mix small quantities of bone cement. Because of these and other problems, there is thus a need for improved systems and methods for mixing and dispensing materials, particularly in the medical field.

One aspect of the invention provides a hand-held systems and associated methods for using the systems, which accurately measure the components before mixing, fully contain the components during mixing (reducing the amount of spilling and noxious fumes released during mixing), mechanically mix or "stir" the cement, and conveniently dispense the mixture.

One aspect of the invention provides an assembly that includes a receptacle for receiving components, e.g., of a bone filling material, in an unmixed condition. The assembly also includes a mixing element that is insertable into the receptacle to mix the components. The assembly further includes an actuator for the mixing element, including a drive member and a driven member coupled to the drive member. The actuator is removably coupled to the

mixing element. After mixing, the receptacle can serve as a dispenser for the materials.

In one embodiment, the mixing element comprises a paddle that mixes components in response to rotation. The paddle can include structure to promote mixing of components, such as, e.g., a plurality of apertures. In this arrangement, the actuator includes a drive member that rotates a paddle. The actuator can include a drive train, e.g., a planetary gear train, that couples a drive member to a driven member. Desirably, the drive member is operable manually.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plane view of a kit that contains the component parts of a system for mixing and dispensing flowable materials that embodies features of the invention;

Figure 2 is a perspective view of a receptacle that forms a part of the system shown in Fig. 1;

Figure 3 is a perspective view of a stand that forms a part of the system shown in Fig. 1;

Figure 4 is perspective side view of an actuator that forms a part of the system shown in Fig. 1;

Figure 5 is a bottom view of the actuator shown in Fig. 4;

Figure 6 is an exploded, perspective view of the actuator shown in Fig. 4;

Figure 7 is a perspective view of one embodiment of a mixing element that forms a part of the system shown in Fig. 1;

Figure 8 is a perspective view of another embodiment of the mixing element that forms a part of the system shown in Fig. 1;

Figure 9 is a perspective view of the receptacle shown in Fig. 2 inserted into the stand shown in Fig. 3, and also showing a component being added to the receptacle;

Figure 10 is a perspective view of the proximal

end of the mixing element shown in Fig. 8 inserted into the exterior side of the lower half of the actuator shown in Fig. 4;

Figure 11 is an exploded view of the actuator, mixing element, receptacle, and stand assembly, as also shown in assembled view in Fig. 12;

Figure 12 is a perspective view of the assembly shown in Fig. 11, showing the actuator grasped by one hand and being manually rotated, and showing the receptacle being grasped by the other hand of the operator, the rotation of the actuator serving to mix materials in the receptacle;

Figure 13 is a perspective view showing the plunger being inserted into the receptacle after the materials have been mixed in the receptacle;

Figure 14 is a perspective view showing the stand being removed from the receptacle prior to dispensing material from the receptacle;

Figure 15 is a perspective view of the plunger inserted into the receptacle containing the material, which is now ready to be dispensed; and

Figure 16 is a perspective view of the material mixed within the receptacle being dispensed from the receptacle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred embodiment describes systems and methods that embody features of the invention in the context of mixing a bone filling material. This is because the systems and methods are advantageous when used for this purpose. It should be appreciated, however, that the systems and methods so described are not limited in their application to the mixing of bone filling material. The systems and methods are applicable for use in diverse applications, both inside and outside the medical field.

I. THE COMPONENT PARTS

Fig. 1 shows component parts, arranged as a kit 200, that are usable in association with each other to form a material mixing and dispensing system. The number and structure of the component parts can vary. In Fig. 1, the kit includes a receptacle 12 for receiving materials for mixing and for, after mixing, dispensing the materials; a mixing element 16 that can be inserted into the receptacle 12 to mix the materials; an actuator 18 to drive the mixing element 16; a plunger 20 that can be inserted into the receptacle 12 to urge mixed materials from the receptacle 12; a dispensing element 22 to dispense the mixed materials urged from the receptacle 12; and a measuring device 24 to measure materials placed in the receptacle 12 for mixing.

Desirably, the components 12, 14, 16, 18, 20, 22 and 24 comprise a substantially rigid metal, plastic or ceramic material. In one embodiment, the components 12, 14, 16, 20, 22 and 24 comprise polypropylene, and component 18 comprises Acetal homopolymer (DELRIN® material from DuPont Corporation) or nylon.

A. The Receptacle

As shown in Fig. 2, the receptacle 12 has a proximal end 30 and a distal end 32. The receptacle 12 further has an interior bore 37 which desirably extends from the proximal end 30 to the distal end 32. The distal end 32 carries a distal tip 34, through which one may dispense a material such as a bone filling material.

The receptacle 12 is sized to separately accommodate the mixing element 16 and the plunger 20 at different stages of the use. The interior surface of the distal tip 34 is sized to support the distal tip 62 of the mixing element 16 during use, as will be described in greater detail later. The proximal end 30 carries a set of tabs 36 on an outer surface 33 of the receptacle 12, to couple the receptacle to the actuator 18, which, in turn, releasably couples to the proximal end of the mixing

element 16. When the plunger 20 is inserted into the receptacle, the tabs 36 also allow the physician to grasp and operate the receptacle 12 and plunger 20 like a syringe, for dispensing materials after mixing, as will be described later.

In one embodiment, the receptacle 12 has a volume of approximately seventy cubic centimeters (70 cc). Of course, other size receptacles could be used, depending upon the size of the mixing element 16 and other associated components, and the desired amount of filler material to be mixed. Other representative sizes could include five (5), ten(10) and twenty (20) cc syringes. The outer surface 33 of the receptacle 12 desirably includes a graduated scale 39 showing the volume inside the receptacle 12. Preferably, the graduated scale 39 begins near the distal tip 34 of the receptacle 12.

If desired, the receptacle 12 may incorporate an attachment for a standard operating room suite vacuum hose, to evacuate fumes produced in the receptacle 12 during the mixing process. If further desired, the receptacle 12 may form a cartridge for a bone filling material delivery gun.

B. The Stand

The stand 14 (see Fig. 3) supports the receptacle 12 during mixing. As shown in Fig. 3, the stand 14 has an upper side 40 and a lower side 42. The upper side 40 has a central neck 44 that is sized to accept and to securely hold the distal end 32 of the receptacle 12. Centered within the neck 44 is a small chamber 46 that is sized to accept the distal tip 34 of the receptacle 12. The lower side 42 of the stand 14 has a flat surface which allows the stand 14 to sit evenly on a surface such as a treatment table.

C. The Mixing Element

The mixing element 16 can be variously configured, and Figs. 7 and 8 show different representative

configurations. In use, the mixing element 16 rotates within the receptacle 12 to mix materials contained in the receptacle.

In both configurations, the mixing element 16 has an upper side 50 and a lower side 52. In one embodiment, the upper and lower sides 50 and 52 have an outwardly extending central rib 51 that acts as a stiffener to maintain integrity of the mixing element 16.

The mixing element 16 has a proximal end 56 and a distal end 57. The distal end 57 desirably carries a flat tip 62 that is adapted to fit into the distal tip 34 of the receptacle 12. The distal tip 62 of the mixing element 16 desirably mixes the components located in the distal tip 34 of the receptacle 12. The distal tip 62 also desirably acts as a bearing surface within the distal tip 34 of the receptacle 12, to keep the mixing element 16 centered within the receptacle 12 as it rotates, as well as constraining side-to-side movement of the mixing element 16 within the receptacle 12.

In the disclosed embodiment, the proximal end 56 carries a solid cylindrical tip 58, although the proximal end 56 could be various configurations suitable for attachment to the actuator 18. The proximal tip 58 is adapted to couple to the actuator 18, as will be described in greater detail later. The proximal tip 58 has a crosspiece 60 that facilitates the transmission of rotational forces from the actuator 18 to the mixing element 16.

The mixing element 16 also desirably has one or more apertures 61, 63, 65, 67, and 69, shown in Figs. 7 and 8. The apertures 61, 63, 65, 67, and 69 function to assist in mixing the chosen components, such as a powdered material and a liquid monomer, together. The apertures 61, 63, 65, 67, and 69 are desirably large enough to allow some of the mixture to flow through the mixing element 16, thereby

allowing the mixing element 16 to rotate within the receptacle 12 with a minimum of resistance and maximizing the mixing of the chosen mixing materials. If the sizes of the apertures 61, 63, 65, 67, and 69 are increased, less resistance to rotation is noted. However, there is a concomitant need for additional rotation of the mixing element 16 in the mixture to ensure thorough mixing. Larger apertures ease the mixing process, while smaller apertures may result in the components "riding up" the mixing element 16. In such a case, the mixing must be stopped momentarily in order to allow the components to fall back into the mixture.

In the embodiment shown in Fig. 8, the mixing element 16 desirably has a series of small, evenly spaced apertures 65 beginning near the proximal end 56 of the mixing element 16, followed by at least two large apertures 69 extending toward the distal end 57 of the mixing element 16, and at least two intermediate sized apertures 67 at the distal end 57. Such an embodiment allows for easier mixing and minimizes the previously mentioned "riding up" of the mixture; however, this embodiment typically requires additional rotations of the component 18. In this embodiment approximately five to twenty rotations of the actuator should be sufficient to ensure a proper mixture in the case of a bone filling material.

In the embodiment shown in Fig. 7, the mixing element 16 has a plurality of evenly spaced apertures 61 that are positioned parallel to the rib 51, and the mixing element 16 further has at least two apertures 63 at the distal tip 62. This embodiment requires approximately five to ten rotations of component 18 to mix a proper bone filling material. Although fewer rotations are needed with this embodiment, this embodiment typically requires more strength for the rotations on behalf of the operator than does the previously mentioned embodiment. Additionally, it

is occasionally necessary to stop during the mixing process to allow the components to fall back into the mixture.

In another alternative embodiment, the mixing element could incorporate one or two large apertures (not shown) extending almost the entire length of the element, similar to the large apertures 69 shown in Figure 8.

D. The Actuator

The actuator 18 (see Figs. 4 and 5) drives the mixing element 16. Desirably, the actuator 18 is formed from DELRIN® material or nylon. As shown in Fig. 4, the actuator 18 is in a palm-sized, cylindrical shape.

The actuator 18 has an outer surface 70 that, if desired, may be knurled or indented to facilitate gripping by the user. The actuator 18 has an upper half 72 and a lower half 74 (see also Fig. 6) that are adapted to be connected with fasteners or, alternatively, can snap-fit together.

The upper half 72 of the actuator 18 functions as a drive member, while the lower half 74 of the actuator 18 is a driven member. The upper half 72 rotates relative to the lower half 74.

Both the upper half 72 and the lower half 74 of the actuator 18 have an interior side 76 and an exterior side 78. As shown in Fig. 6, the interior side 76 of the upper half 72 contains a ring gear 73. The interior side 76 of the lower half 74 contains a planetary gear arrangement 84 that meshes with the ring gear 73.

The planetary gear arrangement 84 includes a sun gear 86 and a plurality of planet gears 88. The sun gear 86 is fixed axially to the lower half 74 of the actuator 18 by means of a screw 95. The planet gears 88 are fixed to a retainer ring 92 by screws 94. In one alternative embodiment, the planet gears 88 would comprise two gears, each gear positioned on opposite sides of the sun gear 86.

The teeth of the planet gears 88 mesh with the teeth

of the ring gear. The teeth of the planet gears 88 also mesh with the sun gear 86. Rotation of the upper half 72 of the actuator 18 relative to the lower half 74 of the actuator 18 rotates the ring gear 73. This, in turn, imparts rotation to the planet gears 88 within the stationary lower half 74 of the actuator 18. Rotation of the planet gears 88, in turn, rotates the sun gear 86 within the lower half 74 of the actuator 18. In the preferred embodiment, a single rotation of the ring gear (i.e., the upper half 72 of the actuator 18) equals approximately four rotations of the sun gear 86 within the lower half 74 of the actuator.

As shown in Fig. 5, the exterior side 78 of the lower half 74 of the actuator 18 has a central slot 96 which receives the end 58 of the mixing element 16. An axle 87 projecting from the sun gear 86 (see Fig. 6) extends into the slot 96. The crosspiece 60 on the end 58 fits into a keyway 89 on the axle 87 (see Fig. 5), which couples the mixing element 16 to the sun gear 86. Thus, rotation of the sun gear 86 imparts rotation to the mixing element 16.

Additionally, the exterior side 78 of the lower half 74 has stabilizing structure 98 (see Fig. 5). The structure 98 abuts against and/or grips the tabs 36 of the receptacle 12 to prevent the receptacle 12 from rotating while rotation is imparted by the sun gear 86 to the mixing element 16. The stabilizing structure 98 is secured to the lower half 74 of the exterior side 78 by fasteners 99. If desired, the actuator 18 may incorporate an attachment for a standard operating room suite vacuum hose (not shown), to evacuate fumes produced during the mixing process.

E. The Plunger

The plunger 20 (see Figs. 13 and 15) fits into the bore 37 of the receptacle 12. Advancement of the plunger 20 within the receptacle 12 expels air from the receptacle 12, as well as dispenses material from the receptacle 12.

F. The Dispensing Element

In one embodiment, the dispensing element 22 comprises a nozzle 100 that is adapted to fit on the distal tip 34 of the receptacle 12 (see Fig. 16). In another embodiment, a LUER® fitting 102 is incorporated into the distal tip 34 of the receptacle 12. In another embodiment, a fitting 104 is incorporated into the distal tip 34 of the receptacle 12, the fitting adapted to mate with the body of a 5 cc or 10 cc syringe. In another embodiment, a tube 106 is incorporated into the distal tip 34 of the receptacle 12, the tube 106 being adapted to fit within a 5 cc or 10 cc syringe body.

G. The Measuring Device

The measuring device 24 is used to measure components before placing the components into the receptacle for mixing. The measuring device 24 may be of a fixed size, such as a 10 cc measuring cup, may be graduated, and/or may include a sieve for sifting particles before mixing.

II. ILLUSTRATIVE USE OF THE SYSTEM

The receptacle 12, stand 14, mixing element 16, actuator 18, plunger 20, dispenser 22 and the measuring device 24, as well as the components to be mixed, are gathered together for use, or are withdrawn as needed from the kit 200 shown in Fig. 1. The physician or an assistant inserts the distal end 32 of the receptacle 12 into the neck 44 of the upper side 40 of the stand 14 (see Fig. 9). Desirably, the distal tip 34 of the receptacle 12 is held within the small chamber 46 located on the upper side 40 of the stand 14, desirably sealing the distal tip 34 closed.

As Fig. 9 shows, the physician may use the measuring device 24 to measure a component to be mixed, such as a powdered component for poly(methylmacrylate) bone cement. The powdered component is poured into the receptacle 12. If the receptacle 12 bears a graduated scale 39 on its outer surface 33, the component can be added to the

receptacle 12 until the desired level is reached. After the powdered component is added to the receptacle 12, another component, such as a liquid monomer for bone cement, is added.

The mixing element 16 and actuator 18 are then obtained. Desirably, the proximal end 56 of the mixing element 16 has been inserted into the slot 96 located on the exterior side 78 of the lower half 74 of the actuator 18 (as Fig. 10 shows). The assembly is now inverted and the distal end 57 of the mixing element 16 inserted into the proximal end 30 of the receptacle 12 (shown in exploded view in Fig. 11). Desirably, the mixing element 16 is inserted such that the distal tip 62 of the mixing element 16 extends into the distal tip 34 of the receptacle 12. The actuator 18 desirably engages with the tabs 36 located on the proximal end 30 of the receptacle 12, so that the lower half 74 of the actuator 18 remains stationary relative to the receptacle 12.

The physician now grasps the upper half 72 of the actuator 18 with one hand, while holding the stand 14, the receptacle 12 or the stand 14 and receptacle 12, with the other hand (see Fig. 12). The upper half 72 of the actuator 18 is then rotated back and forth, first clockwise and then counterclockwise, e.g. (or vica versa), by half-turns, relative to the receptacle 12. Alternatively, or in conjunction with this back and forth motion, , the actuator 18 may be rotated in a single direction. Desirably, the actuator 18 is rotated enough times to adequately mix the mixture.

After the mixture is adequately mixed, the actuator 18 and mixing element 16 are removed from the receptacle 12 and set aside. If desired, the mixing element 16 may be scraped against the top of the receptacle 12 to remove mixture clinging to the element 16, desirably returning such mixture to the receptacle 12. Next, the plunger 20 is

inserted into the proximal end 30 of the receptacle 12 (see Fig. 13). The assembly can now be safely inverted and the stand 14 removed from receptacle 12 (see Fig. 14). Desirably, the stand 14 will not be removed from the receptacle 12 before the step of inserting the plunger 20 and inverting the assembly. In such a case, the mixture, as in the case of a bone filling mixture, could easily flow out of the opening in the distal tip 34 of the receptacle 12.

After the stand 14 is removed from the receptacle 12, air can be expelled from the distal tip 34 of the receptacle 12 by advancing the plunger 20 in the usual fashion of clearing air from a syringe. The mixture may be dispensed directly from the receptacle 12 by advancing the plunger 20. If desired, a dispenser 22 is fitted onto the distal tip 34 of the receptacle 12. In one embodiment, if the dispenser is a nozzle 100, the mixture is dispensed through the nozzle 100. In another embodiment, if the distal tip 34 of the receptacle 12 incorporates a LUER ® fitting 102 , the LUER® fitting may mate with a bone filling material dispensing device as disclosed in U.S. Patent Application Serial No. 09/134,323, which is incorporated herein by reference. When the LUER® fitting 102 is incorporated into the distal tip 34 of the receptacle 12, the combination allows for the direct filling of multiple bone filler devices. In another embodiment, if the distal tip 34 of the receptacle 12 incorporates a fitting 104 that mates with a syringe body of a 5 cc or 10 cc syringe, the syringe may be filled with the mixture in the receptacle 12. In another embodiment, the distal tip 34 of the receptacle 12 may incorporate a tube 106 which fits within a 5 cc or 10 cc syringe body, thus allowing the syringe to be back-filled from the plunger end. In such an embodiment, the tube 106 is inserted through the plunge opening of the syringe. The

syringe is filled from its distal tip to its proximal end, the tube 106 being withdrawn as the syringe fills to a desired level.

If mixture of additional bone filler is desired, or additional bone filler is required after the initial mixture has hardened and/or become unusable, the used mixing element 16 (having cement thereon) may be removed from the actuator 18 and replaced with a new mixing element, allowing the actuator 18 to be used to mix an additional batch of bone filler. In such a case, the kit 200 could contain a single actuator 18 and measuring device 24, with multiple receptacles 12, stands 14, mixing elements 16, plungers 20 and dispensing elements 22 to allow mixing of multiple batches of bone filler.

The features of the invention are set forth in the following claims.